Health Canada Santé Canada

Your health and safety... our priority. *Votre santé et votre sécurité... notre priorité.*

Proposed Registration Decision PRD2014-22

Extract of *Reynoutria sachalinensis*

(publié aussi en français)

31 October 2014

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1925-0878 (print)
1925-0886 (online)

Catalogue number: H113-9/2014-22E (print version)
H113-9/2014-22E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2014

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Table of Contents

Overview 1
Proposed Registration Decision for Extract of *Reynoutria sachalinensis* 1
What Does Health Canada Consider When Making a Registration Decision? 1
What Is Extract of *Reynoutria sachalinensis*? 2
Health Considerations 2
Environmental Considerations 4
Value Considerations 4
Measures to Minimize Risk 4
Next Steps 5
Other Information 5
Science Evaluation 7
1.0 The Active Ingredient, Its Properties and Uses 7
1.1 Identity of the Active Ingredient 7
1.2 Physical and Chemical Properties of the Active Ingredient and End-Use Product 7
1.3 Directions for Use 8
1.4 Mode of Action 8
2.0 Methods of Analysis 9
2.1 Methods for Analysis of the Active Ingredient 9
2.2 Method for Formulation Analysis 9
2.3 Methods for Residue Analysis 9
3.0 Impact on Human and Animal Health 9
3.1 Toxicological Summary 9
3.2 Occupational, Residential and Bystander Risk Assessment 9
3.2.1 Use Description 9
3.2.2 Mixer, Loader and Applicator Exposure and Risk Assessment 9
3.2.3 Postapplication Exposure 10
3.2.4 Residential and Bystander Exposure and Risk 10
3.3 Incident Reports 10
4.0 Impact on the Environment 10
5.0 Value 10
5.1 Effectiveness Against Pests 10
5.1.1 Acceptable Efficacy Claims 10
5.2 Non-Safety Adverse Effects 11
5.3 Consideration of Benefits 11
5.4 Supported Uses 12
6.0 Pest Control Product Policy Considerations 12
7.0 Summary 12
7.1 Human Health and Safety 12
7.2 Environmental Risk 12
7.3 Value 12
8.0 Proposed Regulatory Decision 13

List of Abbreviations 15
Appendix I Tables and Figures 17
Table 1 Active ingredients in alternative fungicides for use on turf to manage foliar anthracnose and dollar spot (as of June, 2014) 17
Table 2 List of Supported Uses 17
References 19

Overview

Proposed Registration Decision for Extract of *Reynoutria sachalinensis*

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of *Reynoutria sachalinensis* Bioprotectant Technical and Regalia Maxx Biofungicide Liquid Concentrate, containing the technical grade active ingredient extract of *Reynoutria sachalinensis*, for partial suppression of dollar spot and foliar anthracnose in turf.

Reynoutria sachalinensis Bioprotectant Technical (Registration Number 30198) and Regalia Maxx Biofungicide Liquid Concentrate (Registration Number 30199) are currently registered in Canada to supress a variety of diseases on field and greenhouse edible crops and ornamentals. The detailed review can be found in Proposed Regulatory Decision PRD 2011-14: *Extract of Reynoutria sachalinensis* as well as Regulatory Decision RD 2012-18: *Extract of Reynoutria sachalinensis*.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment when used in turf.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of *Reynoutria sachalinensis* Bioprotectant Technical (Registration Number 30198) and Regalia Maxx Biofungicide Liquid Concentrate (Registration Number 30199) for use in turf.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

---

1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on extract of *Reynoutria sachalinensis* for use on turf, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on extract of *Reynoutria sachalinensis* for use on turf, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Extract of *Reynoutria sachalinensis*?

The active ingredient is a plant extract from giant knotweed (*Reynoutria sachalinensis*). When sprayed on certain plant species, the extract triggers an induced systemic resistance (ISR) response that acts as an internal defence mechanism against plant pathogens. In turn, this response can suppress the development of disease in treated plants.

Health Considerations

Can Approved Use of Extract of *Reynoutria sachalinensis* on Turf Affect Human Health?

Extract of *Reynoutria sachalinensis* is unlikely to affect human health when used according to label directions.

Potential exposure to extract of *Reynoutria sachalinensis* may occur when handling and applying the product or when people enter a freshly treated site. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

---

3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

The technical grade active ingredient, extract of *Reynoutria sachalinensis*, is anticipated to be of low acute toxicity by the oral, dermal and inhalation routes and minimally irritating to eyes and skin, and not a skin sensitizer. There is no information available in the published scientific literature that suggests extract of *Reynoutria sachalinensis* is carcinogenic, genotoxic, neurotoxic or is a developmental/reproductive toxicant. Moreover, the plant has long been used as a food ingredient and in medicinal products, in some parts of the world, with a history of safe consumption.

The end-use product is of low acute toxicity by oral, dermal, and inhalation routes, is moderately irritating to eyes, mildly irritating to skin, and is not a dermal sensitizer. Due to the irritation potential of the end-use product and the likely exposure of workers and commercial applicators to it via inhalation and contact with skin and eyes, personal protective equipment, precautionary statements, and a restricted-entry statement are required on the label to mitigate any exposure concerns.

Risks in Residential and Other Non-Occupational Environments

Estimated risk for non-occupational exposure is not of concern.

Regalia Maxx Bioprotectant Liquid Concentrate is proposed for use on turf. Consequently, adults, youths and toddlers may be exposed to extract of *Reynoutria sachalinensis* through contact on treated turf. However, risk to the general population is not of a concern since the end-use product is of low toxicity and entry to freshly treated sites is not permitted until sprays have dried.

Occupational Risks From Handling Regalia Maxx Biofungicide Liquid Concentrate for Use in Turf

Occupational risks are not of concern when Extract of *Reynoutria sachalinensis* is used according to label directions, which include protective measures.

Occupational exposure to individuals mixing, loading, or applying Regalia Maxx Bioprotectant Liquid Concentrate is not expected to result in unacceptable risk when the product is used according to label directions. For the bystander, exposure is expected to be much less than that of handlers and mixer/loaders and is considered negligible.

Precautionary (for example, wearing of personal protective equipment) and hygiene statements on the end-use product label aimed at mitigating exposure are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Environmental Considerations

What Happens When Extract of *Reynoutria sachalinensis* is Introduced into the Environment?

***Reynoutria Sachalinensis* is not persistent and the proposed use is not expected to pose a risk to non-target terrestrial or aquatic organisms.**

The active ingredient, extract of *Reynoutria sachalinensis* is a naturally occurring constituent of the plant, *Reynoutria sachalinensis* (common name: giant knotweed). As such, it is expected to break down completely within a relatively short period of time and, therefore, will not be persistent in the environment. Use of Regalia Maxx Biofungicide Liquid Concentrate (containing extract of *Reynoutria sachalinensis*) on turf is not expected to cause adverse effects to non-target terrestrial and aquatic organisms.

Value Considerations

What Is the Value of Regalia Maxx Biofungicide Liquid Concentrate for Use in Turf

Regalia Maxx Biofungicide Liquid Concentrate triggers natural defence mechanisms in treated plants that can suppress the development of certain plant diseases caused by fungal and bacterial pathogens. Preventative application of this product will reduce plant and turf disease development. It is most appropriate for use under low disease pressure. Resistance to the active ingredient is unlikely to develop because of the complex nature of its mode of action. This product can be a valuable component of an integrated disease management program.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Regalia Maxx Biofungicide Liquid Concentrate to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The label has the restricted-entry statement, "Do not re-enter or allow entry into treated areas until the spray is dried."

Next Steps

Before making a final registration decision on Extract of *Reynoutria sachalinensis* for use in turf, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on Extract of *Reynoutria sachalinensis* for use in turf (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Extract of *Reynoutria sachalinensis*

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Extract of *Reynoutria sachalinensis*
Function	Fungicide
Chemical name	
1. **International Union of Pure and Applied Chemistry (IUPAC)**	Not applicable
2. **Chemical Abstracts Service (CAS)**	Not applicable
CAS number	Not applicable
Molecular formula	Not applicable
Molecular weight	Not applicable
Structural formula	Not applicable
Purity of the active ingredient	100% nominal

1.2 Physical and Chemical Properties of the Active Ingredient and End-Use Product

Technical Product—*Reynoutria Sachalinensis* Bioprotectant Technical

Property	Result
Colour and physical state	Olive green, brown and cream solid
Odour	Not applicable
Melting range	Not applicable
Boiling point or range	Not applicable
Density	0.135 ± 0.004 g/mL
Vapour pressure at 20°C	Not applicable
Ultraviolet (UV)-visible spectrum	Not applicable
Solubility in water at 20°C	Not applicable
Solubility in organic solvents at 20°C (g/100 mL)	Not applicable
n-Octanol-water partition coefficient (K_{ow})	Not applicable

Property	Result
Dissociation constant (pK_a)	Not applicable
Stability (temperature, metal)	Not applicable

End-Use Product—Regalia Maxx Biofungicide Liquid Concentrate

Property	Result
Colour	Brown
Odour	Characteristic of plant extract/grass-like odour
Physical state	Liquid
Formulation type	Liquid
Guarantee	20% nominal
Container material and description	Polyvinyl chloride (PVC) bottles and jugs, 1 to 50 L
Density	1.123 g/mL
pH of 1% dispersion in water	5-6
Oxidizing or reducing action	The EP is not expected to have any oxidizing or reducing properties.
Storage stability	Not applicable
Corrosion characteristics	The EP is not expected to be corrosive.
Explodability	The EP is not expected to be explosive.

1.3 Directions for Use

Regalia Maxx Biofungicide Liquid Concentrate is to be applied on turf preventatively or at the first appearance of disease at a concentration of 0.25% (on a volume basis) in 1000 to 1500 litres of water per hectare. The product may be reapplied at seven to ten day intervals, depending on disease pressure, and should be used in rotation with other products that are registered to manage the same diseases.

1.4 Mode of Action

In treated plants, the extract of *Reynoutria sachalinensis* triggers an internal defence response referred to as induced systemic resistance (ISR). A complex reaction involving various chemical responses within plants, ISR can inhibit the development of plant diseases that are caused by various fungal and bacterial pathogens. Repeated applications are recommended to maintain ISR in host plants. Induction of the defense response by the extract of *Reynoutria sachalinensis* is reported to take one to two days.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

A non-validated analytical method was provided for the analysis of one of the compounds present in the active ingredient and was assessed to be acceptable for the determination.

2.2 Method for Formulation Analysis

Based on the nature of the product this requirement is waived.

2.3 Methods for Residue Analysis

Not applicable.

3.0 Impact on Human and Animal Health

3.1 Toxicological Summary

Refer to Proposed Registration Decision PRD2011-14, *Extract of Reynoutria sachalinensis* for a detailed review of the toxicology of the technical product and the end-use product.

3.2 Occupational, Residential and Bystander Risk Assessment

3.2.1 Use Description

Regalia Maxx Biofungicide Liquid Concentrate is proposed as a foliar spray on turf. The end-use product is to be applied by commercial pesticide applicators using spraying equipment commonly used for making ground applications at a rate of 0.25% v/v in 1000-1500 L of water/ha. Re-application is proposed every seven to ten days as needed.

3.2.2 Mixer, Loader and Applicator Exposure and Risk Assessment

The proposed application rate and frequency of application of Regalia Maxx Biofungicide Liquid Concentrate are consistent with those currently on the registered label. No changes to the existing personal protective equipment (PPE) will be required as a result of the addition of the major new use to the registered label.

Occupational exposure to Regalia Maxx Biofungicide Liquid Concentrate is not expected to result in unacceptable risk when workers follow label directions. The registered label has necessary exposure reduction statements (for example, personal protective equipment (PPE), clothing, hygiene statement) which are considered adequate to protect workers against any unnecessary risk from exposure from the application of Regalia Maxx Biofungicide Liquid Concentrate to turf.

3.2.3 Postapplication Exposure

Postapplication exposure is possible when workers or people enter treated turf soon after the application. The primary exposure route for early entry workers and other individuals is dermal from contact with freshly treated surfaces. To mitigate such potential exposure, the registered label restricts entry into treated areas until sprays have dried. Therefore, postapplication exposure from the treated turf is not expected to be of concern.

3.2.4 Residential and Bystander Exposure and Risk

As the commercial application involves only authorized personnel, bystander exposure is expected to be negligible when the end-use product is used according to the label directions.

Based on the proposed use on turf, adults, youths and toddlers may be exposed to extract of *Reynoutria sachalinensis* through contact with treated turf. However, risks to the general population, including children and infants, is not of a concern since the end-use product is of low toxicity and the end-use product label requires people to avoid freshly treated sites until the sprays have dried. In addition, the label instructs applicators to limit spray drift to neighbouring properties.

3.3 Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the Health Canada website. Incidents were searched for products containing the active ingredient extract of *Reynoutria sachalinensis*. As of 6 March 2014 there were no health-related incident reports for this active ingredient.

4.0 Impact on the Environment

Refer to Proposed Registration Decision PRD2011-14, *Extract of Reynoutria sachalinensis* for a detailed review of impact on the environment.

5.0 Value

5.1 Effectiveness Against Pests

5.1.1 Acceptable Efficacy Claims

Evidence of product effectiveness against turf diseases was provided in the form of efficacy trial data. Claims for partial suppression of foliar anthracnose and dollar spot were supported with data from one and two trials, respectively. All turf trials were conducted in 2010 in the state of Michigan.

Partial suppression of foliar anthracnose

Statistically significant reductions in the percentage of turf area infected by foliar anthracnose were noted in the extract of *Reynoutria sachalinensis* treatment relative to untreated control treatments. A slight yet significant increase in turf quality was also observed later in the assessment period. Although evidence of Regalia Maxx Biofungicide Liquid Concentrate efficacy against this disease comes from a single trial, the information provided was deemed sufficient since the trial was conducted under representative conditions (for example, acceptable disease pressure) and the results were consistent at the different assessment dates.

Partial suppression of dollar spot

Evidence of Regalia Maxx Biofungicide Liquid Concentrate efficacy against dollar spot on turf was obtained under low and high disease pressure. Reductions in the severity of dollar spot were reported in two efficacy field trials. Improvements in quality ratings were also reported for turf preventatively treated with extract of *Reynoutria sachalinensis*. In one instance, the quality of the turf was improved by the treatment to the point of reaching minimal commercially acceptable ratings, whereas the untreated turf was rated as commercially unacceptable.

5.2 Non-Safety Adverse Effects

Phytotoxicity resulting from applications of extract of *Reynoutria sachalinensis* on turf was not reported in any of the trials provided. There is no indication that non-safety adverse effects would pose a concern when Regalia Maxx Biofungicide Liquid Concentrate is applied to turf in accordance with label directions and restrictions.

5.3 Consideration of Benefits

The evidence showing Regalia Maxx Biofungicide Liquid Concentrate effectiveness against turf disease was assessed in the context of other factors that contribute to the value of this registration. The product can become a useful element in integrated turf pest management programs by reducing disease pressure and thereby potentially minimizing amounts of conventional chemical fungicides applied seasonally. It will provide a very important tool to manage turf diseases for which non-conventional fungicides are not currently registered. This consideration is particularly important in the case of turf producers and managers that aim to avoid the use of conventional chemical pesticides. For instance, this registration of Regalia Maxx Biofungicide Liquid Concentrate may provide a valuable addition to commercial home lawn care companies operating in provinces where the use of cosmetic pesticides are not allowed. Refer to Table 1 for a survey of alternative products registered for the management of these turf diseases.

Further, because of the putative mode of action of the active ingredient, which relies on a complex array of biological responses within the treated plants, the risk of disease resistance development by target pathogens can be assumed to be very low.

5.4 Supported Uses

The value of applying Regalia Maxx Biofungicide Liquid Concentrate on turf preventatively to partially suppress foliar anthracnose and dollar spot has been demonstrated.

6.0 Pest Control Product Policy Considerations

Refer to Proposed Registration Decision PRD2011-14, *Extract of Reynoutria sachalinensis* for a detailed review of the Toxic Substances Management Policy Considerations.

7.0 Summary

7.1 Human Health and Safety

The toxicology profiles of the registered Reynoutria Sachalinensis Bioprotectant Technical and Regalia Maxx Biofungicide Liquid Concentrate remain unchanged.

The occupational exposure to Regalia Maxx Biofungicide Liquid Concentrate from the proposed use on turf is expected to be minimal if the precautionary statements and required personal protective equipment on the product label, which are intended to minimize worker exposure, are observed. The health risk to the general population, including infants and children, as a result of bystander exposure is expected to be minimal due to the low toxicity of extract of *Reynoutria sachalinensis* and the requirement to avoid contact with freshly treated areas until sprays have dried.

7.2 Environmental Risk

Reynoutria sachalinensis is a plant extract (common name: giant knotweed) and is not expected to be persistent in the environment. *Reynoutria sachalinensis* is a natural food source for many terrestrial invertebrates and vertebrates. It has been shown to be harmless to beneficial arthropods, including predators, parasites and honeybees, to mammals and is not toxic to birds as many species have been found to consume the seeds of the plant. The exposure to aquatic organisms is not likely to be greater than from naturally occurring stands of *R. sachalinensis* in the environment

7.3 Value

The value information available, which was primarily in the form of efficacy data and considerations of other benefits, was determined to be sufficient to support the value of registering the use on turf for the end use product Regalia Maxx Biofungicide Liquid Concentrate. The product will be used for the partial suppression of two important turf diseases, dollar spot and foliar anthracnose.

Registration of the use Regalia Maxx Biofungicide Liquid Concentrate on turf will provide a non-conventional option to users with demonstrated effectiveness in reducing turf disease. Use of this product can be easily incorporated into an integrated disease management program. Few to no biologically based products are currently registered for the various major turf diseases in Canada. This product will be of particular value for turf producers and managers aiming to avoid the use of conventional synthetic fungicides.

8.0 Proposed Regulatory Decision

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of *Reynoutria sachalinensis* Bioprotectant Technical and Regalia Maxx Biofungicide Liquid Concentrate, containing the technical grade active ingredient extract of *Reynoutria sachalinensis*, for partial suppression of dollar spot and foliar anthracnose in turf.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

Human Health

The label has the restricted-entry statement, "Do not re-enter or allow entry into treated areas until the spray is dried."

List of Abbreviations

µg	micrograms
1/n	exponent for the Freundlich isotherm
a.i.	active ingredient
ADI	acceptable daily intake
ALS	acetolactate synthase
ARfD	acute reference dose
atm	atmosphere
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetres
DF	dry flowable
DNA	deoxyribonucleic acid
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in concentration)
DT_{75}	dissipation time 75% (the dose required to observe a 75% decline in concentration)
EC_{10}	effective concentration on 10% of the population
EC_{25}	effective concentration on 25% of the population
ER_{25}	effective rate for 25% of the population
g	gram
ha	hectare(s)
HDT	highest dose tested
Hg	mercury
HPLC	high performance liquid chromatography
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_d	soil-water partition coefficient
K_F	Freundlich adsorption coefficient
km	kilometre
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*–octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOAEL	lowest observed adverse effect level
LOEC	low observed effect concentration
LOQ	limit of quantitation
LR_{50}	lethal rate 50%
mg	milligram
mL	millilitre
MAS	maximum average score
MOE	margin of exposure
MRL	maximum residue limit
MS	mass spectrometry
N/A	not applicable

NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NOER	no observed effect rate
N/R	not required
NZW	New Zealand white
OC	organic carbon content
OM	organic matter content
PBI	plantback interval
PHI	preharvest interval
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppm	parts per million
RSD	relative standard deviation
SC	soluble concentrate
$t_{1/2}$	half-life
T3	tri-iodothyronine
T4	thyroxine
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
UAN	urea ammonium nitrate
UF	uncertainty factor
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v/v	volume per volume dilution

Appendix I Tables and Figures

Table 1 Active ingredients in alternative fungicides for use on turf to manage foliar anthracnose and dollar spot (as of June, 2014).

Disease	Active Ingredient (FRAC Resistance Management Group)
Foliar anthracnose (*Colletotrichum cereale*)	azoxystrobin (11)
	azoxystrobin (11) + propiconazole (3)
	Bacillus subtilis, strain GB03(44)[1]
	fosetyl AL (U)
	fluoxastrobin (11)
	mineral oil (NC)[1]
	penthiopyrad (7)
	propiconazole (3)
	propiconazole (3) + chlorothalonil (M)
	pyraclostrobin (11)
	chlorothalonil (M)
	trifloxystrobin (11)
Dollar spot (*Sclerotinia homoeocarpa*)	azoxystrobin (11) + propiconazole (3)
	Bacillus subtilis, strain GB03(44)[1]
	boscalid (7)
	fluoxastrobin (11)
	iprodione (2)
	mineral oil (NC)[1]
	myclobutanil (3)
	penthiopyrad (7)
	propiconazole (3)
	propiconazole (3) + chlorothalonil (M)
	pyraclostrobin (11)
	chlorothalonil (M)
	thiophanate-methyl (1)

[1] Non-conventional pesticides

Table 2 List of Supported Uses

Proposed use claim	Supported Use
Partial suppression of foliar anthracnose caused by *Colletotrichum cereale* on turf at a rate of 0.25% v/v in 1000-1500 liters of water per hectare, repeated as necessary at intervals of 7 to 10 days.	Supported as proposed
Partial suppression of dollar spot caused by *Sclerotinia homoeocarpa* on turf at a rate of 0.25% v/v in 1000-1500 liters of water per hectare repeated as necessary at intervals of 7 to 10 days.	Supported as proposed

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
1773484	2009, DACO 2 Chemistry Requirement for Registration of a Technical Grade of Active Ingredient (TGAI), DACO: 2.1,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9 CBI
1773485	2009, DACO 2.11.1 Manufacturing Summary, DACO: 2.11.1 CBI
1773486	1999, Manufacturing Data Requirement Supporting Milsana Bioprotectant Concentrate and Reynoutria sachalinensis bioprotectant, DACO: 2.11.2,2.11.3,2.12.1,2.13.1,2.13.2,2.13.3 CBI
1773487	1999, Evaluation of the Biological Activity of Milsana for Control of Cucumber Powdery Mildew and Validation of the Bioassay Technique, DACO: 2.13.1,2.13.2,2.13.3 CBI
1773488	1999, Selected Group B Analyses for Dried Planet Material of Reynoutria sachalinensis, Lot # 11-89/2A, DACO: 2.14.1,2.14.2,2.14.3,2.14.6 CBI
1773489	2000, Supporting Data to Address Preliminary Analysis of TGAI an Use Product Containing Reynoutria sachalinensis, Lot # 11-89/2A, DACO: 2.14.14 CBI
1773490	2009, DACO 2 Chemistry Requirement for the Registration of a Technical Grade of Active Ingredients (TGAI), DACO: 2.14.10,2.14.11,2.14.12,2.14.13,2.14.4,2.14.5,2.14.7,2.14.8,2.14.9 CBI
1773491	1999, Supplemental Public Literature Studies Supporting the Registration Application for Milsana Bioprotectant Consentrate and Reynoutria sachalinensis Bioprotectant for Nonfood Greenhouse Use, DACO: 2.16 CBI
1836417	2009, MANUFACTURING PROCESS FOR EXTRACT OF REYNOUTRIA SACHALINENSIS, DACO: 2.11.3 CBI
1836418	2009, Reynoutria sachalinensis Bioprotectant Technical, Sub. 2009-2189, DACO: 2.11.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8 CBI
1836421	2009, Flow Chart, DACO: 2.11.3 CBI
1921448	2010, Determination of Physcion in the Dry Ethanolic Extract of Reynoutria sachalinensis by High Performance Liquid Chromatography, DACO: 2.13.1 CBI
1921449	2010, Certificate of Analysis, DACO: 2.13.3 CBI
1979329	2010, Reynoutria sachalinensis TGAI-Clarification, DACO: 2.13.3 CBI
2029407	2010, CERTIFICATE OF ANALYSIS, DACO: 2.12.1 CBI
2029408	2011, MANUFACTURING PROCESS FOR REYNOUTRIA SACHALINENSIS BIOPROTECTANT TECHNICAL, DACO: 2.11.3 CBI
1773563	2009, DACO 3.1.1-3.1.4, DACO: 3.1.1,3.1.2,3.1.3,3.1.4 CBI
1773564	2009, Product Chemistry for Regalia Max, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9 CBI

1773565	1999, Evaluation pf the Biological Activity of Milsana for Contro;l of Cucumber Powdery Mildew and Validation of the Bioassy Technique, DACO: 3.4.1 CBI
1773566	2009, DACO 3.5.4 FORMULATION TYPE, DACO: 3.5.4 CBI
1773567	2009, DACO 3.5.5 CONTAINER MATERIAL AND DESCRIPTION, DACO: 3.5.5 CBI
1816850	2009, Letter, DACO: 3.2.2
1816852	2009, Corrosion Characteristics of Regalia Maxx, DACO: 3.5.14 CBI
1816853	2009, Miscibility of Regalia Maxx, DACO: 3.5.13 CBI
1816854	2009, Viscosity of Regalia Maxx, DACO: 3.5.9 CBI
1816855	2009, Oxidizing and REducing Action of Regalia Maxx, DACO: 3.5.8 CBI
1921604	2010, Product Chemistry for Regalia Maxx, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.4.1,3.4.2,3.5.1,3.5.10,3.5.11,3.5.13,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9 CBI

2.0 Human and Animal Health

2307676 2013, Use Description/Scenario For REGALIA MAX (Submitted In Support Of DACO 5.2), DACO: 5.1.5.2,5.3

2307677 2013, Part 5, EXPOSURE, DACO: 5.3,5.4,5.5

3.0 Value

2291339 2013, Summary of Experiments Examining the Performance of Regalia for Control of Disease in Peppers, Cucumbers, Tomatoes, Blueberries, Apples, Strawberries, Turf and Ornamentals, DACO: 10.1,10.2.3.1,10.3.1

2291340 2013, Summary of Trials Evaluating Regalia, DACO: 10.1,10.2.3.1,10.3.1